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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,868	07/21/2004	Jean-Pierre Devidal	021305-00201	8688

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EXAMINER	
ALSTRUM ACEVEDO, JAMES HENRY	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 10/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/500,868	DEVIDAL ET AL.	
	Examiner	Art Unit	
	James H. Alstrum-Acevedo	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7,8 and 10-16* is/are pending in the application.

4a) Of the above claim(s) *10-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7 and 8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-5, 7-8, and 10-16 are pending. ***Claims 1-5 and 7-8 are under consideration in the current office action.*** Receipt and consideration of Applicants' amended claims and remarks/arguments, submitted on July 24, 2006 is acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

The rejection of claims 1-3 and 7-8 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is withdrawn** per Applicants' amendments correcting indefinite language and ranges. Claims 6 and 9 were previously rejected under 35 U.S.C. 112, 2nd paragraph, but because these claims have been cancelled this rejection **is moot**.

The rejection of claims 4-5 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is maintained** for the reasons of record as set forth on pages 2-3 of the previous office action mailed on March 23, 2006.

Claim 4 is vague and indefinite, because it lacks antecedent basis for "the step consisting of...spraying a liquid onto an area to be treated..." Claim 4 depends from claim 1, which prior to amendment recited a step consisting of spraying a liquid. Newly amended claim 1 recites a step "comprising" the step of abrading the stratum corneum followed by spraying a pressurized liquid.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejections of (1) claims 1-5 under 35 U.S.C. 102(b) as being anticipated by Bode et al. (DE 19606433; English abstract only); (2) claims 1-4 and 6 under 35 U.S.C. 102(b) as being anticipated by the commercially available product OFF!®; and (3) claims 1-4 and 9 under 35 U.S.C. 102(b) as being anticipated by Fitzjarrell (U.S. Patent No. 5,989,523) **are withdrawn**, per Applicants' amendments introducing the limitations of original dependent claims 6 and 9 into independent claim 1.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejections of (1) claims 2-3 under 35 U.S.C. 103(a) as being unpatentable over Bode et al. (DE 19606433; English abstract only) in view of Yu et al. (5,962,526); (2) claim 9 under 35 U.S.C. 103(a) as being unpatentable over Bode et al. (DE 19606433; English abstract only) in view of Rhoades (US 2001/0018061); (3) claims 6-7 under 35 U.S.C. 103(a) as being unpatentable over Bode et al. (DE 19606433; English abstract only) in view of Hirota (U.S. Patent No. 5,894,963); and (4) claim 8 under 35 U.S.C. 103(a) as being unpatentable over Bode et al. (DE 19606433; English abstract only) in view of Yu et al. (5,962,526), and further in view of Laughlin (U.S. 2002/0000237) **are withdrawn**, per Applicants' amendments introducing the limitations of original dependent claims 6 and 9 into independent claim 1.

Claims 1-5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bode et al. (DE 19606433; based on the English abstract and translation) in view of Rhoades (US 2001/0018061) and Hirota (U.S. Patent No. 5,894,963).

Applicant Claims

Applicants claim a method for the treatment of an area of human skin comprising the steps of (i) abrading a portion of the stratum corneum (i.e. the outermost layer of skin) followed by spraying a pressurized liquid onto the area to be treated by means of a spray nozzle and sucking the sprayed liquid with an intent to discharge, wherein the liquid comprises water or saline (claim 2) or at least one additive (claim 3), wherein the spraying step comprises spraying a liquid at a maximum pressure such that there is no risk of breaking the skin (claim 4), at a pressure of between 5-70 bar (claim 5), and wherein the suction step is performed by reducing pressure of a volume surrounding the treated area of skin (claim 7).

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Bode (only the English abstract was cited in the previous office action), Rhoades, and Hirota were set forth on pages 4-5 (Bode), 9-10 (Rhoades), and 10-12 (Hirota), respectively, in the previous office action mailed on January 10, 2006. However, many of these teachings are set forth again herein for Applicants' convenience. Bode teaches a device using a pneumatic or hydraulic pressure medium for applying a treatment product in the form of a cream, **liquid**, or gas to the **required skin area via an application jet** (abstract). The treatment product comprises pharmaceuticals or cosmetics (pg. 3, 3rd paragraph of translation; translated claim 1).

The pressure of the **pressure medium can be adjusted between 0 and 8 bar**, in a number of discrete steps, with the treatment product mixed with the pressure medium, or applied to the skin before application of the jet. A schematic of the device disclosed by Bode, comprising a nozzle (137), is also present in the abstract. It is noted that liquid cosmetics inherently contain water. Creams also inherently contain additives, which is interpreted as being anything other than the active compound, including solvents, such as water.

Rhoades teaches a composition including a base and a plurality of abrasive particles, an apparatus suitable for **contacting localized areas of human skin**, and a method including **applying a composition to an area of human skin**, the composition comprising a base and a plurality of abrasive particles, and manipulating the composition over the area of human skin with a handle-operated instrument (abstract).

Rhoades teaches in [0004] that **microdermabrasion (e.g., microexfoliation, particle skin resurfacing)** is a technique in skin care in which a controlled exfoliation of the skin is performed to improve and remove skin abnormalities. A typical microdermabrasion machine consists of a compressor to project inert crystals of corundum through a tube into a hand piece across the skin with variable pressure while the hand piece is in contact with the skin. **This induces an abrasion action, which removes the top layer of skin**. At the same time, through another tube within the hand piece, the used corundum and abraded skin are vacuumed into another container for disposal. The removal of the outer layer of skin induces the human body to produce a new layer of skin, which is believed to improve the skin subject to treatment, including the appearance of wrinkles, acne, scars, age spots, damaged skin, etc [0013]. Rhoades teaches that a principal component of his invented composition includes a moisturizer, which includes

humectants, such as glycerin, alpha hydroxy acids, etc. [0014]. Suitable moisturizers may be in the form of liquids, creams gels, pastes, and emollients. Rhoades' invented compositions may be applied with Rhoades invented apparatus, described in [0031].

Hirota teaches a pump mechanism for ejecting liquid, which can eject a fixed amount of a given liquid, such as a liquid medicine, at a time in the form of a spray or jet. Containers for holding a liquid medicine for nose or throat treatment, for instance, are usually provided with a built-in pump mechanism for ejecting the liquid medicine on affected parts of a human body (col. 1, lines 5-11).

Hirota teaches that when the force which has been applied to the operating nozzle head 60 is removed, a restoring force of the spring 17 causes the second piston 30, first piston 20 and operating nozzle head 60 to move upward back to their home positions (FIG. 1). Since **a negative pressure** (i.e. suction) is produced inside the metering chamber A at this point, **a mass of liquid is sucked from the container 50 into the metering chamber A by way of the suction tube 13, the intake port 12b in the stationary cylinder 10, the small-diameter portion 12, axial hole 33 and nonreturn valve 34** (col. 5, lines 28-33). A tube, wherein a liquid is suctioned, reads on an annular suction chamber.

Hirota teaches that the inventive pump mechanism is suited for a wide variety of liquid ejecting applications in which a liquid is ejected in either a solid stream or a fine mist, including liquid medicines for nose and throat treatment, **liquid cosmetic products**, detergent, oil, etc. (col. 7, lines 11-16).

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

Bode lacks the teaching of a method of treatment wherein the *stratum corneum*, the outer layer of skin, is abraded, and including a step of "sucking the sprayed liquid." These deficiencies are cured by the teachings of Rhoades and Hirota, respectively.

Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to combine the teachings of Bode, Rhoades, and Hirota because all references teach methods and/or devices for treating skin or applying compositions intended for the treatment of skin, including cosmetic and pharmaceutical compositions. A skilled artisan would have been motivated to combine the teachings of Rhoades with those of Bode, because the skin microexfoliation (i.e. abrasion of the stratum corneum) resulting from application of Rhoades' composition would promote the improvement of undesirable skin aesthetics by inducing the growth of a new outer layer of skin in the treated area. It would have been apparent to a skilled artisan that it is desirable to apply Rhoades' composition and exfoliate the outer layer of skin as an initial step in skin treatment, because this would promote the growth of a new layer of skin and the improvement of undesirable skin appearance. Regarding the teachings of Hirota, a skilled artisan would have been motivated to combine the teachings of Hirota with the teachings of Bode, because Bode teaches a device for the application of a liquid treatment product and Hirota teaches a pump mechanism suited for applications in which a liquid, including a liquid cosmetic product, is ejected either as a solid stream or a fine mist. A person of ordinary skill in

the art at the time of the instant invention would have had a reasonable expectation of success upon combination of the prior art references, because both Bode's and Hirota's inventions are suitable for the application liquid products to areas of the skin and Rhoades' compositions/methods are designed for skin treatments.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bode et al. (DE 19606433; based on the English abstract and translation) in view of Rhoades (US 2001/0018061) and Hirota (U.S. Patent No. 5,894,963) as applied to claims 1-5 and 7 above, and further in view of Laughlin (U.S. 2002/0000237) and/or Yu et al. (5,962,526).

Applicant Claims

Applicants claim a method for the treatment of an area of human skin comprising the steps of (i) abrading a portion of the stratum corneum (i.e. the outermost layer of skin) followed by spraying a pressurized liquid onto the area to be treated by means of a spray nozzle and sucking the sprayed liquid with an intent to discharge, wherein the method further comprises the steps of filtering the liquid and recycling it (claim 8).

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Bode, Rhoades, and Hirota have been set forth above in the instant office action. Laughlin teaches a system for coating human skin, a chemical composition, such as a cosmetic or medical formulation, is uniformly coated over the entire body or selected parts of the body of the person being coated (abstract). Laughlin teaches that the final element of this

invention is **recovery, or filtering, of residual composition**. This feature greatly enhances the utility of the invention because it allows the system to be self-contained in an indoor environment and promotes a more environmentally friendly process. One configuration of the recovery system is shown in Fig. 5 [0210].

Yu teaches a composition and method for enhancing therapeutic effects of topically applied agents are disclosed. The **cosmetic or therapeutic composition** may include one or more of cosmetic or pharmaceutical agents present in a total amount of from 0.01 to 40 percent and **one or more of hydroxycarboxylic acids or related compounds** present in a total amount of from 0.01 to 99 percent by weight of the total composition. Any hydroxyacid and related compound may be used as an **additive** in a combination composition **to enhance percutaneous penetration** or the therapeutic efficacy of cosmetic and pharmaceutical agents (col. 6, lines 27-30). The therapeutic compositions are prepared in solution form by dissolution of at least one hydroxyacid and a cosmetic or pharmaceutical agent with solvents including **water** or other pharmaceutically acceptable vehicle (col. 6, lines 63-67 and col. 4, line 1). The therapeutic compositions may also be prepared in **cream or ointment form** by conventional mixing of a therapeutic solution of Yu's invention with an appropriate cream or ointment base (col. 7, lines 6-12). Therapeutic compositions in the form of a gel or spray may also be formulated (col. 7, lines 15-16).

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

Bode lacks the teaching of a method of treatment wherein the method further comprises the steps of filtering and recycling the liquid. Bode lacks the express teaching of a liquid comprising water or saline and/or at least one additive.

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to combine the teachings of Bode, Rhoades, Hirota, and Yu, because Bode, Rhoades, and Hirota teach methods and/or devices for treating skin or applying compositions intended for the treatment of skin, including cosmetic and pharmaceutical compositions, including products in the form of a cream or liquid, and Yu teaches cosmetic/pharmaceutical compositions which may be topically applied to the skin. It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to combine the teachings of Bode, Rhoades, Hirota, and Laughlin, because Laughlin teaches systems intended for application of compositions to the skin. A skilled artisan would have been motivated to combine the teachings of Bode, Rhoades, and Hirota and with the teachings of Yu, because Yu's compositions, which may be topically applied, were shown to achieve a substantial increase in cosmetic or therapeutic effect of the active ingredient in humans and domesticated animals and Bode's device was designed to apply a treatment product to the skin. A skilled artisan would have been motivated to incorporate the steps of filtering and recovery of the residual composition in Bode's device to promote a more environmentally friendly process. Furthermore, it is known in the art that excess sprayed liquid can be recovered from the application site by incorporation of a vacuum line into the spray device (See Weber et al. US 2002/0058952). It is also common knowledge in the art

that excess material may be removed from the application site by absorption (i.e. being "sucked up") via the use of a washcloth, pad, cotton ball, or other application device (see Meisner et al. US 2002/0037314 paragraph [0064]). The phrase "with an intent to discharge it" does not require that the absorbed or "sucked up" liquid is actually discharged, rather that it could be discharged. The term "discharge" reads on any process wherein the absorbed/sucked up liquid is emitted or released, such as would occur in routine washing of a sponge or washcloth, for example. For the reasoning set forth above, a person of ordinary skill in the art at the time of the instant invention would have had a reasonable expectation of success. The Examiner concludes that claim 8 is *prima facie* obvious over the combined teachings of the prior art and what is commonly known in the art.

Response to Arguments

Applicant's arguments filed July 24, 2006 with regards to the rejection of claims 4-5 under 35 U.S.C. § 112, 2nd paragraph have been fully considered but they are not persuasive. Applicants' argue that claim 4 is not missing essential elements (i.e. the required pressure of the sprayed liquid such that there is no risk of breaking the skin in the treated area), because the necessary pressure would have been obvious in light of the teachings of the specification and said pressure could also be readily determined by a person of ordinary skill in the art at the time of the instant invention. The Examiner respectfully disagrees, because Applicants' specification does not teach at what pressure or pressure ranges one would expect a subject's skin to break. Rather Applicants' teach that the device disclosed in their application may spray a liquid having a pressure ranging from 5-70 bar (pg. 4, lines 11-14), and this does not clarify to a skilled artisan

what would constitute suitable pressure ranges. Furthermore, it would be an undue burden for a skilled artisan if they had to test each individual to determine the appropriate required pressure, due to inherent differences in skin differences between individuals. Applicants' have asserted that the amendments to claim 5 corrected the indefinite ranges. The Examiner respectfully disagrees, because the language of claim 5 still recites ranges within ranges (i.e. "...pressure is between 5 and 70 bar, preferably between 10 and 25 bar.").

Applicant's arguments with respect to claims 1-5 and 7-8, regarding the art rejections of record, have been considered but are moot in view of the new ground(s) of rejection.

Other Matter

The Examiner has noted that claim 8 is improper multiple dependency, because it depends from claims 1-5 and 7 and claim 4 also depends from multiple claims (i.e. claims 1-3). The Examiner respectfully suggests correcting the improper dependency of claim 8.

Conclusion

Claims 1-5 and 7-8 are rejected. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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